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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/464,039	12/15/99	MEYERS R	5800-49

EXAMINER	
KAUSHAL S	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/464,039	MEYERS, RACHEL	
	Examiner	Art Unit	
	Sumesh Kaushal	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-86* is/are pending in the application.

4a) Of the above claim(s) *68-71,74-76 and 80-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-67,72,73,78 and 79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The preliminary amendment filed on 06/04/01 is aknowledged and entered.

Election/Restrictions

Applicant's election with traverse of Group IV claims 61-67 and 72-73 in Paper No. 7 filed 06/04/01 is acknowledged. The traversal is on the ground(s) that nucleic acid of Group IV (claims 77-79) are also used in the method of detecting the presence of nucleic acid of Group XIX. This is found persuasive and claims 77-79 of Group XIX are joined with Group IV. Claims 61-67, 72-73 and 77-79 are examined in this office action.

The requirement is still deemed proper and is therefore made FINAL.

Claims 68-71, 74-76 and 80-86 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 61-67, 72-73 and 77-79 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The instant claims are drawn to an isolated nucleic acid molecule comprising a nucleic which is at least 45% identical to nucleic acid sequence of SEQ ID NO: 8. The claims are further drawn to a nucleic acid sequence which encodes a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO:7. The claims are drawn to a nucleic acid molecule, which encodes a naturally occurring allelic variant of a polypeptide comprising the amino acid sequence of SEQ ID NO: 7 or an amino acid sequence encoded by a nucleic acid molecule which hybridize to nucleic acid molecule comprising SEQ ID NO: 8. The claims are drawn to vector ad host cells containing the nucleic acid of SEQ ID NO:8 and method of producing the polypeptide of SEQ ID No:7. In addition the claims are drawn to a method for detecting the presence of a nucleic acid molecule and a kit for the detection of the nucleic acid of SEQ ID NO: 8 or its variants.

The instant invention is not considered to have a specific and/or substantial utility because the specification fails to establish that the disclosed polynucleotide sequences encodes an amino acid which is an human alcohol dehydrogenase (AHD) as shown by structural and/or functional properties. The recited SEQ ID NO(s) are simply computer-generated hypotheses, wherein no biological function has been established. It is known in the art that Alcohol dehydrogenase (ADH) constitutes a complex enzyme system with different forms and extensive multiplicity and the range of the biochemical reactions which can be catalyzed by ADH is extremely wide (Duester, Eur. J. Biochem 267:4315-4324, 2000, see page 4316 table 1, 2, page 4317-4319). The specification fails to show a single working example that establishes that the SEQ ID NO: 8 which encodes the amino acid sequence of SEQ ID NO:7 is a member of Alcohol dehydrogenase (ADH) family, such as by any substantial sequence homology and/or functional assay of the protein.

The specification alleges that the instant nucleic acid encodes an Alcohol dehydrogenase (ADH). However, no sequence comparisons are taught by specification as filed, nor are any specific similarities to other know ADH are disclosed, such as common areas of conservation. The specification fails to teach that polypeptide encoded by claimed SEQ ID NO: 7 have any ADH-like biological activity explicitly or implicitly as putatively considered by the specification.

The only immediate apparent utility for the instant invention would be its further scientific characterization as a putative inhibitor of appoptosis protein like activity.

Furthermore, One skilled in the art would not readily attribute any ADH-like activity encoded by the instant nucleic acid in view of the low sequence similarity and the lack of sequence conservation therein. At best the Office sequence search using the disclosed amino acid sequences (SEQ ID NO:8) matches with a hypothetical protein belonging to ribitol-dehydrogenase super-family from C. elegans (AC. NO. T19954) and a human alcohol dehydrogenase (AC. NO. AA622988) but with only 41.7% and 12.7% sequence similarity respectively. Further inspection of the comparison shows limited if any areas of conservation between the two sequences. In view of such and the fact that ADH differs substantially in activity, it is unclear that any ADH-like activity could be attributed to the deduced amino acid sequence of the claimed nucleic acid sequences. Therefore, the asserted use for the claimed nucleic acid is not considered to support by either a specific and/or substantial utility, since no function can be ascribed to the gene.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61-67, 72-73 and 77-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is described above in section 101 rejection. As per section 101 rejection above, applicants fails to provide any evidence that the nucleic acid sequences as

disclosed has any functionality, even though an ORF has been identified. However, a sequence search for ORF did not reveal any related genes. Thus, no function based on similarity can be attributed to the nucleic acid as claimed

Furthermore, the claimed invention is drawn to the polypeptide encoded by the nucleic acid sequences which hybridize to nucleic acid sequence of SEQ ID No:8 or have 45% sequence identity to SEQ ID NO:8. The variants as claimed encompass 55%-98% nucleotide sequence variation over the entire of SEQ ID NO: 8 (see claim 61 and 72). The variation also encompasses the conserved motifs that are germane to the ADH specific biological activity. The specification fails to disclose the association of polypeptide of SEQ ID NO:7 with any and all disease. Furthermore, the specification fails to identify any allelic variants of SEQ ID NO:7 required for the phenotypic manifestation of any and all disease associated with the polypeptides of SEQ ID NO:7. Therefore, it is unclear how one skill in the art would the invention as claimed.

The claimed invention is not enabled in view of lack of teachings in the specification as filed regarding what additional sequences may be added, deleted or substituted to those specifically disclosed, such that asserted utility discussed in the section 101 rejection above would be recognized as specific and/or substantial. The specification as filed only teaches nucleic sequence of SEQ ID NO:8 which encodes the amino acid sequence of SEQ ID NO:7 and fails to provide guidance that any and all variants of SEQ ID NO:7 which are capable of eliciting any ADH-like activity. It is general knowledge in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if amino acids that are critical for such functions are substituted, and the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable. The recited SEQ ID NO(s) are simply computer-generated hypothesis because no biological function has been established. The mere identification of critical regions would not be sufficient, as the ordinary artisan would immediately recognize that the encoded polypeptide must assume the proper three-dimensional configuration to be active, which is dependent upon the surrounding residues. Therefore, applicant has not presented enablement commensurate in scope with the claims.

In addition the invention as claimed encompass a host cells in vivo which contains the claimed nucleic acid sequences (see claim 65-66). Therefore, the invention reads upon a cell obtained by a method of gene therapy or a cell present in a transgenic animal. The art at the time of filing clearly teaches that the Gene therapy is considered highly experimental area of research at this time, and both researchers and the public agree that demonstrable progress to date has fallen short of initial expectations (Rosenberg et al, Science 287:1751, 2000). Similarly, the state of transgenic art at the time of filing was such that phenotype of an animal is determined by a complex interaction of genetics and environment. (Wood. Comp. Med. 50(1): 12-15, 2000, see page12). Therefore, it would require an undue amount of experimentation to exercise the invention as claimed. Claims drawn to an isolated host cell would obviate this rejection.

In addition, it is unclear how one skill in the art would use the invention as claimed when applicant's referral to the deposit of ATCC PTA-2170 on page 5 of the specification is insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met (see attachment).

Claims 61 and 72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to an isolated nucleic acid molecule comprising a nucleic which is at least 45% identical to nucleic acid sequence of SEQ ID NO: 8. The claims are further drawn to a nucleic acid sequence which encodes a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO:7. In addition the claims are drawn to a nucleic acid molecule, which encodes a naturally occurring allelic variant of a polypeptide comprising the amino acid sequence of SEQ ID NO: 7 or an amino acid sequence encoded by a nucleic acid molecule which hybridize to nucleic acid molecule comprising SEQ ID NO: 8.

The specification as fails to disclose any and all variant of human alcohol dehydrogenase comprising the nucleic acid sequence of SEQ 8, which encodes the amino acid sequences of SEQ ID NO:7. The specification discloses only one variant of ADH-like polypeptide within the scope of genus comprising the claimed SEQ ID NO(s). The specification proposes to discover other members of the genus using hybridization procedure. However, there is no description of mutational sites that exist in nature, and there is no description how the structure of identified nucleic acid sequences relates to the structure of any strictly neutral alleles. In addition, the ADH-like polypeptide include members that would expected to have widely divergent functional properties. The general knowledge in the art concerning ADH-like protein does not provide any indication as how the structure of one allele is representative of other unknown amino acid sequences having concordant or discordant functions. The commons attributes of the ADH protein are not described, and identifying attributes of individual ADH-like protein other than SEQ ID NO: 8 as claimed are not described. The nature of ADH-like protein is that they are variant structures and functions of others (Duester, Eur. J. Biochem 267:4315-4324, 2000, see page 4316 table 1, 2, page 4317-4319). The specification only disclosed nucleic acid sequence of SEQ ID NO: 8 which encodes the amino acid sequence of SEQ ID NO:7. The specification fails to describe any and all variants of nucleic and amino acid sequences of SEQ ID NO(s) as claimed. According to these facts, one skill in the art would conclude that applicant was not in the possession of the claimed genus because a description of only one member of this genus is not representative of the variants of genus and is insufficient to support the claim.

Claims 61-67, 72-73 and 77-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 61 recites the limitation "the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-2170, or a complement thereof" in lines 4-5, 7-8, 10-11, 13-14. There is insufficient antecedent basis for this limitation in the claim.

Claims 62 recites the limitation "the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-2170, or a complement thereof" in lines 4-5, 7-8. There is insufficient antecedent basis for this limitation in the claim.

Claims 72 recites the limitation "the cDNA insert of the plasmid deposited with ATCC as Patent Deposit Number PTA-2170, or a complement thereof" in lines 4-5, 7-8, 9-10 and 12-13. There is insufficient antecedent basis for this limitation in the claim.

Claim 79 is indefinite because it is unclear what is "the compound" which selectively hybridize with nucleic acid as claimed. In addition, claim 79 is indefinite because it is unclear what are the "instructions for use" in this context.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 61, 77 and 78 is rejected under 35 U.S.C. 102(b) as being anticipated by NCI-CGAP (Gene Bank AC. No. AA622988, 1997). NCI-CGAP teaches an isolated nucleic acid sequence encoding an Alcohol dehydrogenase, which comprises at least 15 nucleotides of SEQ ID NO:8 or can be used as probe to detect the nucleic acid sequence of SEQ ID NO:8 of instant application (see PTO sequence search report). Thus the cited art clearly anticipate the invention as claimed.

Conclusion

No claims are allowed.

Claims 61-67, 72-73 and 77-79 are free of prior art of record. The prior art does not teach or suggest nucleic acid of SEQ ID NO: 8 encodes a human alcohol dehydrogenase as depicted in SEQ ID NO:7.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-6838. The examiner can normally be reached on Monday-Friday from 9:00 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Deborah Clark can be reached on (703) 305-4051. The fax-phone number for the organization where this application or proceeding is assigned as (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Tracey Johnson, whose telephone number is (703) 308-0377. If the claims are amended canceled and/or added the applicants are required to follow Amendment Practice under 37 CFR § 1.121 *(http://www.uspto.gov)* and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED to facilitate further examination.

SUMESH KAUSHAL
PATENT EXAMINER

SUMESH KAUSHAL
PATENT EXAMINER

Deposit Requirement

Applicant's referral to the deposit of ATCC PTA-2170 on page 5 of the specification is insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met.

> If the deposit was made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by Applicant, Assignee, or a statement by an attorney of record over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository, is required. This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty, as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required.

Furthermore, unless deposit was made at or before the time of filing, a declaration filed under 37 CFR 1.132 is necessary to construct a chain of custody. The declaration, executed by a person in a position to know, should identify the deposited material by its depository accession number, establish that the deposited material is the same as that described in the specification, and establish that the deposited material was in Applicant's possession at the time of filing. See In re Lundak, 27 USPQ 90.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request, or for the enforceable life of the patent, whichever is longer;
d) a test of the viability of the biological material at the time of the deposit was made, and that the test results indicated that said biological material was viable (see 37 CFR 1.807); and,
e) the deposit will be replaced it should ever become inviable.

-:-